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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHN O'DONNELL, RUTHANN HILLAND, and MICHELE DE SCISCIOLO, for themselves and a class of consumers similarly situated, Plaintiffs, v. KRAFT FOODS INC., SARA LEE CORPORATION, CONAGRA FOODS, INC., NATHAN'S FAMOUS, INC., and MARATHON ENTERPRISES, INC., Defendants.	No. 09 Civ. 4448 (JLL)(CCC) **ORAL ARGUMENT REQUESTED** *Filed Electronically*

MEMORANDUM OF LAW IN SUPPORT OF THE JOINT MOTION OF DEFENDANTS KRAFT FOODS INC., SARA LEE CORPORATION, CONAGRA FOODS, INC., NATHAN'S FAMOUS, INC., AND MARATHON ENTERPRISES, INC. TO DISMISS THE COMPLAINT

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Defendants Kraft Foods, Inc., Sara Lee Corporation, ConAgra Foods, Inc., Nathan's Famous, Inc., and Marathon Enterprises, Inc. (collectively "Defendants"), by and through their undersigned counsel, and pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b), submit this Memorandum in Support of their Joint Motion to Dismiss the Class Action Complaint filed by John O'Donnell, Ruthann Hilland, and Michele De Scisciolo (collectively "Named Plaintiffs") for themselves and a class of consumers similarly situated (collectively "Plaintiffs").

PRELIMINARY STATEMENT

Plaintiffs' putative Class Action Complaint ("Complaint") asserts one cause of action under the New Jersey Consumer Fraud Act ("CFA"), N.J. Stat. Ann. § 56:8-1 *et seq.*, and seeks damages for the Named Plaintiffs and an injunction for the Class preventing Defendants from selling or marketing and advertising hot dogs and other "processed meat products" in New Jersey without disclosing that consumption of those products may – according to the Complaint – increase a person's risk of certain types of cancer. Compl. ¶ 1. While the Complaint identifies brand name hot dogs that the Named Plaintiffs allegedly purchased, *id.* ¶¶ 26-30, it does not identify any other processed meat products that Plaintiffs purchased. As the basis for their claim that Defendants' processed meat products have been reported as being associated with increased cancer risk, Plaintiffs refer only to publicly available articles that do not mention Defendants' products and that make no allegations regarding specific types, amounts and effects of the actual ingredients in any of Defendants' processed meat products, including hot dogs.

Plaintiffs' Complaint should be dismissed. Because Congress has vested all authority for insuring the health and safety of the country's meat and meat products with the United States Department of Agriculture ("USDA") pursuant to the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 601 *et seq.*, Plaintiffs' state law claim is preempted pursuant to the express preemption

doctrine, the field preemption doctrine, and the implied conflict preemption doctrine.[1] To the extent Plaintiffs' claim is not preempted, the case should be dismissed and referred to the USDA pursuant to the primary jurisdiction doctrine. Plaintiffs' CFA claim also must be dismissed for failure to state a claim because under New Jersey law, claims for alleged harm related to consumer products must be brought, if at all, under the New Jersey Products Liability Act ("PLA"), N.J. Stat. Ann. § 2A:58C-1 *et seq.*, and not the CFA. Even if this was not true, the claim still must be dismissed because Plaintiffs fail to properly plead the necessary elements of a cause of action under the CFA.

BACKGROUND

The Complaint generally alleges that Defendants unlawfully concealed from consumers that the consumption of hot dogs and other processed meat products is a "major contributor to the risk" of developing certain forms of cancer. Compl. ¶ 1. Plaintiffs broadly define "processed meat products" as those "prepared and/or preserved by curing, smoking, salting or adding chemical preservatives, such as nitrites," and allege that those products include "hot dogs, ham, bacon, pastrami, salami, bologna, liverwurst, bratwurst sausage, luncheon meat, and, depending on the processing, hamburgers and minced meats." *Id.* ¶ 2. While the Complaint contains allegations that the three Named Plaintiffs *purchased* on average one to four packages of hot

[1] Defendants cannot discern from Plaintiffs' broad definition of "processed meat products" (i.e. "those prepared and/or preserved by curing, smoking, salting or adding chemical preservatives, including nitrites"), Compl. ¶ 2, whether the definition includes poultry products manufactured by any Defendant. To the extent that any of the processed meat products at issue here contain poultry, however, the legal analysis is identical under the federal Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 451 et seq. The PPIA creates a federal regulatory scheme for poultry products which is virtually identical to that of the FMIA, including an express preemption provision, 21 U.S.C. § 467e, that is identical to the corresponding FMIA provision, 21 U.S.C § 678. Moreover, courts rely on decisions interpreting the preemption provisions of the FMIA and PPIA interchangeably when deciding preemption issues under either statute. *See*, e.g., *Nat'l Broiler Council v. Voss*, 44 F.3d 740, 745-46 (9th Cir. 1994) (California law prohibiting use of the word "fresh" on labels for poultry products unless poultry was stored at more than 26 degrees imposes requirement "in addition to" labeling requirements of PPIA, and therefore preempted).

dogs per month, the Complaint is completely silent regarding Plaintiffs' purchases of other processed meat products and does not allege the quantity of processed meat actually consumed. *Id.* ¶¶ 21-23.

In an effort to support these allegations, Plaintiffs refer to a number of published and publicly available research studies that purport to analyze the correlation between consumption of processed meat products and certain health risks. *Id.* ¶¶ 4, 33. Plaintiffs acknowledge that the cited studies do not determine the specific molecular or biological mechanism that allegedly links consumption of processed meat products to colorectal and other cancers, but nevertheless state that the studies hypothesize that the linkage mechanism "may involve *N*-nitroso compounds, nitrites, or high levels of salt." *Id.* ¶¶ 4-5, 34-36. Plaintiffs claim that because processed meat products "are often prepared" using nitrites and Defendants' products "likely contain nitrites," Defendants had a duty to warn customers about risks associated with their products. *Id.* ¶¶ 2, 8, 9.

Notably, while making these claims, Plaintiffs ignore the fact that the USDA has regulated nitrites in meat products for more than 100 years. Over that time period, the USDA itself, as well as in collaboration with the Food and Drug Administration ("FDA") and expert panels, has studied whether the presence of nitrites and nitrates in meat products is unsafe or may increase the chances of developing cancer. *See, e.g.*, 40 Fed. Reg. 52614 (Nov. 11, 1975); Nitrates and Nitrites in Poultry Products, Statement of Policy, 42 Fed. Reg. 44376 (Sept. 2, 1977); Nitrates and Nitrites in Meat Products, 42 Fed. Reg. 55626 (Oct. 18, 1977); Nitrates, Nitrites, and Ascorbates (or Isoascorbates) in Bacon, 43 Fed. Reg. 20992 (May 16, 1978); 45

Fed. Reg. 59870 (Sept. 5, 1980).[2] *See also National Pork Producers Council v. Bergland*, 631 F.2d 1353 (8th Cir. 1980). While results from those studies have from time to time caused the USDA to adjust the amount of these ingredients that can be used in meat products since it first regulated them around 1907,[3] USDA has continued to permit the use of various nitrate and nitrite salts in meat products. *See* Nitrates and Nitrites in Meat and Poultry Products, 48 Fed. Reg. 1702, 1704 (Jan. 14, 1983) (to be codified at 21 C.F.R. pt. 181). Among the nitrates and salts also approved by the USDA as curing agents or other additives to meat are sodium and potassium nitrate, 9 C.F.R. § 424.21(c), as well as sodium and potassium nitrite. *Id*. at § 424.22(a)(1).

Based on the extensive study of nitrate and nitrite salts, on January 14, 1983, the FDA adopted a final rule "codifying the prior sanctions issued by USDA for the use of nitrates and nitrites in meat and poultry products." 48 Fed. Reg. at 1702. This rule was promulgated

> based on determinations by USDA that: (1) Nitrates and nitrites may be used in cured red meat products to fix color and to serve as a preservative under the terms of a prior sanction granted under the FMIA (21 U.S.C. 96), and (2) the use of nitrates and nitrites as a preservative and color fixative in poultry products was sanctioned and approved by USDA under the PPIA (21 U.S.C. 451 *et seq.*) prior to September 6, 1958.

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[2] The Court should take judicial notice of Federal Register publications. 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed."); *see also Getty Petroleum Marketing, Inc. v. Capital Terminal Co.*, 391 F.3d 312, 325 n.19 (1st Cir. 2004); *United States v. Woods*, 335 F.3d 993, 1001 (9th Cir. 2003). On a motion to dismiss, the court may take judicial notice of matters of public record without converting the motion to dismiss into a motion for summary judgment. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-689 (9th Cir. 2001).

[3] *See*, e.g., 40 Fed. Reg. 52614 (Nov. 11, 1975) (authorizes direct addition of nitrite to meat products, but permits no more than 200 ppm of residual nitrite in finished product); 43 Fed. Reg. 20992 (May 16, 1978) ("Panel recommended the adoption of the 120 ppm sodium nitrite level and simultaneous use of sodium ascorbate or sodium erythorbate at 550 ppm"). *See Public Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980).

Id. at 1702-03. The FDA also determined that nitrates and nitrites, when used as a color fixative and preservative in meat and poultry, are not food additives under the Federal Food, Drug, and Cosmetic Act ("FDCA"). *Id*. at 1703-04.

By ignoring the USDA's extensive study of nitrates and its regulation of their use in meat products and instead relying on their own uninformed predicates, Plaintiffs contend that Defendants have knowingly and intentionally exposed Plaintiffs to an increased risk of cancers in violation of the CFA. Compl. ¶¶ 2, 31, 50, 56. The Complaint seeks (1) recovery by the Named Plaintiffs of the $900 they allegedly combined to spend on Defendants' hot dogs, (2) an injunction requiring conspicuous placement on all packaging, point of sale marketing, and Internet and New Jersey-based advertising of Defendants' processed meat products sold in New Jersey, the statement: "WARNING: CONSUMING HOT DOGS AND OTHER PROCESSED MEATS INCREASES THE RISK OF CANCER" and (3) attorney's fees. *Id.* ¶¶ 14-16, 24 and Prayer for Relief.

ARGUMENT

I. PLAINTIFFS' CLAIM IS PREEMPTED UNDER THE SUPREMACY CLAUSE OF THE CONSTITUTION OF THE UNITED STATES.

Plaintiffs allege that Defendants violated the New Jersey CFA by (1) intentionally omitting material information about their processed meat products in order to affect sales, and (2) failing to post conspicuously specific labels or warnings with respect to alleged cancer risks associated with their processed meat products. Because Congress has made plain that all issues relating to the preparation, marketing and labeling of meat and meat products are governed exclusively by the FMIA as administered by the USDA, this state law claim is preempted by federal law.

Under the Supremacy Clause in Article VI, clause 2 of the Constitution of the United States, federal law may preempt state law under any of three forms of the preemption doctrine: express preemption, field preemption, and implied conflict preemption. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) (citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)). Express preemption arises when Congress expressly articulates the extent to which a federal statute preempts state law. *Lindsey v. Caterpillar, Inc.* 480 F.3d 202, 205 (3d Cir. 2007). Field preemption applies when state law "regulates conduct in a field that Congress intended the federal government to occupy exclusively." *English*, 496 U.S. at 79; *Lindsey*, 480 F.3d at 205. And, implied conflict preemption arises when either "it is impossible . . . to comply with both state and federal requirements," or "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79; *see Lindsey*, 480 F.3d at 205-06. Plaintiffs' state law claim must be dismissed under express, field and implied preemption.

A. The Federal Meat Inspection Act Creates a Comprehensive National Scheme for Regulation of Meat and Meat Products.

In 1907, in response to concerns over the safety of meat and meat products, Congress enacted the FMIA, 21 U.S.C. § 601 *et seq.*, to ensure the safety of the nation's food supply and to minimize the risk to public health from potentially dangerous meat food products. *See* 21 U.S.C. § 602 ("[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated and properly marked, labeled, and packaged."); *United States v. Stanko*, 491 F.3d 408, 416-17 (8th Cir. 2007) (FMIA's primary public-health purpose is to protect consumers from unsafe meat). The FMIA sets forth an elaborate federal regulatory scheme for the inspection of

animals, the examination of the sanitary conditions of establishments where animals and meat are processed, and inspection of meat products prepared for commerce. The purpose of this regulatory scheme is to prevent the shipment of impure, adulterated, unwholesome and unfit meat and meat products in interstate and foreign commerce and to prohibit the sale of meat or meat food products under any false or deceptive name, marking or labeling.

The FMIA sets out stringent requirements for labeling of meat or meat food products. The packages of meat products inspected and passed for commerce, for example, must be labeled as "inspected and passed." 21 U.S.C. § 607(a). Products inspected and found not to be adulterated must bear the information required under the misbranding provisions of the act. 21 U.S.C. § 607(b); *see also* 21 U.S.C. §601(n) (setting forth "misbranding" provisions). Only products that have marking, labeling, and containers that are not false or misleading and that are approved by the Secretary of Agriculture may be distributed in commerce. 21 U.S.C. § 607(d).

The FMIA manifests a clear Congressional intent that the national standards of identity and composition of meat food products be uniform in their application, *see* 21 U.S.C. § 601(n)(7), and provides the Secretary of Agriculture with expansive authority to establish labeling and composition standards, as well as the duty to make such rules and regulations as are necessary for the execution of the Act. *See* 21 U.S.C. § 607. Among many other prerogatives, the statute specifically enables the Secretary of Agriculture to prescribe labeling requirements, definitions and standards of identity to avoid false or misleading labeling, as well as definitions and standards of identity and composition whenever the Secretary determines such action is necessary to protect the public. 21 U.S.C. § 607(c); *see, e.g., National Pork Producers Council v. Bergland*, 631 F.2d 1353 (8th Cir. 1980) (USDA properly exercised its authority when it issued regulations permitting nitrate and nitrate-free meat and meat products to be sold under

product names traditionally reserved for foods containing these compounds, and set forth composition and labeling requirements for uncured products); *Houston v. St. Louis Independent Packing Co.*, 249 U.S. 479 (1919) (Secretary of Agriculture had power to determine whether trade name was false or deceptive, and his decision, unless arbitrary, was conclusive).

To allow successful implementation of uniform national standards with respect to marking, labeling, packaging and ingredient requirements related to meat products, Congress expressly prohibited the states from imposing any requirement that is different than or exceeds the standards set forth under the federal statute. Specifically, the FMIA provides that:

> Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter.

21 U.S.C § 678. Through this language, Congress expressly preempted states from placing any additional or different requirements on meat producers from those imposed by the federal government through the FMIA. *See, e.g., Jones v. Rath Packing Co.*, 430 U.S. 519, 532 (1977) (California law regarding net weight labeling that made no allowance for moisture loss was preempted by the FMIA); *Grocery Manufacturers of America v. Gerace*, 755 F.2d 933, 1002-03 (2d Cir. 1985) (New York law that mandated precise size of letter and relative location of the word "imitation" on package labels preempted by FMIA); *Armour & Co. v. Ball*, 468 F.2d 76, 84 (6th Cir. 1972) (Michigan statute on marking, labeling, packaging and ingredient standards for processed meats preempted by the FMIA); *Animal Legal Defense Fund v. Provimi Veal Corp.*, 626 F. Supp. 278, 285 (D. Mass. 1986) (FMIA preempts Massachusetts statute requiring warning of potential harmful effects of "genetically-altered" bacteria contained in veal from animal feed).

B. Plaintiffs' State Law Claim Is Expressly Preempted by the Federal Meat Inspection Act.

When a federal statute contains an explicit preemption provision, the Court must "identify the domain expressly preempted" by that language. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (internal quotations omitted). However, given the breadth of the USDA's explicit authority to regulate the "marking, labeling, packaging, or ingredient requirements" of meat under the FMIA, 21 U.S.C § 678, Plaintiffs' state law claim – that Defendants intentionally omitted material information about their processed meat products and failed to post conspicuously specific labels or warnings with respect to the alleged cancer risks of those products in violation of the CFA – obviously is expressly preempted. Plaintiffs' Complaint and requested relief here plainly seek to affect "marking, labeling, packaging, or ingredient requirements" of meat products in a manner that imposes requirements "in addition to, or different than" the requirements established by the USDA under the FMIA.

While the FMIA does allow for limited concurrent state jurisdiction to enforce its requirements, states are not permitted to enact their own labeling requirements for regulated meat products. *See Armour & Co.* 468 F.2d at 84 ("the concurrent action of a state … only applies to adulterated or misbranded articles"); *Kraft Foods N. Am. v. Rockland County Dep't of Weights & Measures,* No. 01 Civ. 6980, 2003 U.S. Dist. LEXIS 2714, at *16 (S.D.N.Y. Feb. 26, 2003). Rather, the FMIA permits states to exercise concurrent jurisdiction with the Secretary of Agriculture over articles required to be inspected under the FMIA for the narrow purpose of "preventing the distribution for human food purposes of any such articles which are adulterated or misbranded" under federal law. *Id.* Meat is considered "adulterated" if it "bears or contains . . . any added poisonous or added deleterious substance (*other than one which is . . . a food additive*. . .) which may, *in the judgment of the Secretary*, make such article unfit for human

food," or if "it bears or contains any food additive which is unsafe within the meaning of [21 U.S.C. § 348]." 21 U.S.C. § 601(m)(2)(A, C) (emphasis added). A product is "misbranded" if, among other things, "its labeling is false or misleading in any particular." 21 U.S.C. § 601(n)(1) .

Although Plaintiffs claim that Defendants' processed meat products contain additives which are "known or reasonably anticipated human carcinogens such as nitrites and N-nitroso compounds," Compl. ¶ 5, Plaintiffs are careful not to allege that these salts and compounds are unsafe within the meaning of 21 U.S.C. § 348, or unfit for human consumption. To do so would run directly afoul of USDA regulations and rules promulgated by the FDA which expressly permit these substances to be used as food additives in meat products. *See* 9 C.F.R. § 424.22(a)(1) (permitting nitrates and nitrites, including sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, to be added to meat). And nothing in the FMIA permitting concurrent state jurisdiction allows a state to substitute its judgment for the judgment of the Secretary of Agriculture regarding food safety.[4]

Characterizing their claims as "misbranding" rather than "adulterated" plainly does not avoid the effects of the express preemption doctrine either. Plaintiffs contend that the labeling of Defendants' processed meat products is "misleading and false" because it fails to provide information or warnings about the alleged cancer risk of consuming their products. Compl. ¶ 47. They maintain that under the CFA this "misbranding" requires Defendants to include a cancer warning label on their retail packages, point of sale advertising in New Jersey, websites and Internet advertisements. Compl. ¶¶ 16, 24. However, because the USDA permits Defendants to

[4] The State of New Jersey, which regulates food produced or sold within the state, N.J. Stat.Ann. § 24:1-1 et seq., has approved the presence of these substances in food. Under New Jersey law, any food that conforms to the federal FDCA is deemed in conformity with the NJFDL and regulations thereunder. Id. at § 24:1-4.

market and sell their processed meat products without including on their packaging or labeling the warning proposed by Plaintiffs, requiring such a warning under the CFA unquestionably would be "in addition to, or different than" the marking, labeling and packaging requirements under the FMIA, and thus expressly preempted. *See* 21 U.S.C § 678.

Not only does the FMIA preempt Plaintiffs' state law claim seeking the placement of warnings on retail packages of processed meat products, it also preempts any request that warnings be required on point-of-sale materials, or other written, printed or graphic matter "accompanying" the processed meat products. *See* 21 U.S.C. §601(p) (defining "labeling" under the FMIA as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article").

In *Animal Legal Defense Fund v. Provimi Veal Corp.*, for example, the Animal Legal Defense Fund ("ALDF") alleged that Provimi violated the Massachusetts consumer protection statute by not informing consumers that its calves were mistreated and fed antibiotic drugs, and sought an order requiring Provimi to provide this information to consumers. 626 F. Supp. at 278-79. Dismissing the complaint, the district court concluded that it was "unnecessary to reach the merits of the ALDF's claims … because they are preempted by the comprehensive federal scheme regulating the labeling, packaging and marketing of meat and the use of medicated animal feeds," embodied in the FMIA and the federal FDCA. *Id.* at 281-83.

The Third Circuit, along with a number of other courts, have held that the term "labeling" must be given broad meaning to include printed materials, even if the product and the literature were not actually attached to each other. *See United States v. 47 Bottles*, 320 F.2d 564, 568 (3d Cir. 1963) ("the term 'labeling' must be given a broad meaning 'to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the

article.'"); *V.E. Irons, Inc v. United States*, 244 F.2d 34, 38-39 (1st Cir. 1957) ("there is no doubt that the printed circulars, pamphlets, brochures and newsletters distributed by appellant in the present case constituted 'labeling' within the statutory definition."). And, in *Jones v. Rath Packing Co*., 430 U.S. 519, 532 (1977), the U.S. Supreme Court expressly rejected the argument that the authority granted to the USDA over food labeling referred only to the formatting and placement of information, not the accuracy of its contents, finding the argument "strained," and noting that "[n]othing in the Act suggests [this] restrictive meaning." *Id*.

Plaintiffs seek to require warnings not required by the FMIA on Defendants' retail packages of processed meat products and promotion and advertising of such products at Defendants' sales locations. The warnings that Plaintiffs claim are mandated by the CFA would impose a requirement "in addition to, or different than" the federal labeling requirements imposed by the FMIA, and are precisely the sort of labeling requirements expressly preempted under those federal statutes. Because Plaintiffs do not assert any claim not subject to the express preemption provision of the FMIA, Plaintiffs' Complaint should be dismissed with prejudice in its entirety.[5]

[5] This analysis is not changed by the Third Circuit's recent decision in *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009), where the court found no field preemption or implied conflict preemption, but did not rule on express preemption, over a CFA claim that Snapple misled consumers by promoting as "all natural" beverages that contained high fructose corn syrup. Snapple cited both the federal FDCA and the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 *et seq.*, as the basis for preemption claims, but the court found that the NLEA expressly stated that it did not preempt any state law and that the FDCA did not contain an express preemption clause signaling a Congressional intent to occupy the field of beverage labeling. In contrast, the FMIA expressly states that "marking, labeling, packaging or ingredient requirements in addition to, or different than those made under [Chapter 12 (Meat Inspection)] may not be imposed by any State." *See* 21 U.S.C. § 678. Thus, unlike the federal statutes at issue in Holk, the FMIA preemption provision does not carve out certain labeling provisions that the state law may or may not preempt, but instead requires state regulation to be identical to the entire federal regulatory scheme as it relates to labeling of meat products subject to the FMIA.

C. Plaintiffs' CFA Claim Also Is Barred by the Field Preemption Doctrine And the Implied Conflict Preemption Doctrine.

Field preemption applies where "the depth and breadth of a congressional scheme … occupies the legislative field," while implied conflict preemption applies where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856, 863 (9th Cir. 2009). As already noted, the FMIA provides a comprehensive statutory framework to ensure that meat and meat food products prepared for sale at commerce are wholesome, not adulterated, and are properly labeled and packaged. *See, e.g., Nat'l Meat Ass'n v. Brown*, CV-F-08-1963, 2009 U.S. Dist. LEXIS 12523, at *15 (E.D. Cal. Feb. 19, 2009) (FMIA provides "an elaborate system" of inspection and labeling with the goal of preventing the shipment of unwholesome, adulterated, or improperly marked, labeled, or packaged meat or meat food products.). The FMIA explicitly provides that "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia." 21 U.S.C. § 678. This statutory language expresses an unmistakable intent to fully occupy the legislative field with respect to marking, labeling, packaging, and ingredient requirements for meat products. To hold otherwise would render the FMIA's clear statutory language of no practical effect and would ignore an evident Congressional objective to place all authority for implementing marking, labeling, packaging and ingredient requirements for meat products with the federal government.

To allow the various states to impose additional or different label requirements also would frustrate the Congressional purpose of establishing national and uniform standards of identity and composition for meat products. *See* 21 U.S.C. § 601(n)(7). Requiring a warning label not determined to be necessary by the USDA regarding an expressly permitted food

additive plainly would undermine the statutory scheme and present undeniable obstacles to accomplishing the Congressional objectives in enacting the FMIA.

The reach and comprehensive nature of the FMIA and its implementing regulations, by themselves, establish that Congress intended to fully occupy the field of "marking, labeling, packaging, and ingredient requirement" of processed meat products. To allow individual states, through common law causes of action, to impose labeling and warning requirements in addition to those deemed necessary by the federal authorities would frustrate these clearly articulated Congressional purposes and objectives. Consequently, even if this Court were to find that the FMIA does not expressly preempt Plaintiffs' state law claim, the claim should be deemed subject to field preemption, implied conflict preemption, or both, and Plaintiffs' Complaint should be dismissed with prejudice.

II. PLAINTIFFS' STATE LAW CLAIM SHOULD BE DISMISSED UNDER THE PRIMARY JURISDICTION DOCTRINE.

To the extent Plaintiffs' claim is not preempted, the case should be dismissed pursuant to the primary jurisdiction doctrine.

In order to promote the "proper relationship between the courts and administrative agencies charged with particular regulatory duties," the primary jurisdiction doctrine is applied when enforcement of a claim "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63-64 (1956); *see Campione v. Adamar, Inc.*, 714 A.2d 299, 308 (N.J. 1998). Under the doctrine of primary jurisdiction, a court may defer a decision to a particular agency whose expertise is required to resolve the questions presented. *See Campione*, 714 A.2d at 308; *IPCO Safety Corp. v. WorldCom, Inc.*, 944 F. Supp. 352, 357-58 (D.N.J. 1996) (applying doctrine of primary jurisdiction to refer issues to the FCC for resolution

because of its expertise in telecommunications). When the court determines that referral to an administrative agency is appropriate, the court "has discretion either to retain jurisdiction or, if the parties would not be unfairly disadvantaged, to dismiss the case." *Reiter v. Cooper*, 507 U.S. 258, 268-69 (1993).

The essential purposes of the doctrine of primary jurisdiction are "the promotion of uniformity and consistency in the regulation of a business entrusted to a particular agency, the utilization of an agency's specialized knowledge and insight gained through experience, and the exercise of administrative discretion in affecting regulatory policy entrusted to an agency." *IPCO Safety Corp.*, 944 F. Supp. at 356, citing *AT&T Co. v. People's Network, Inc.*, No. 92 Civ. 3100, 1993 U.S. Dist. LEXIS 21248, *11 (D.N.J. March 31, 1993). A court *should* refer a matter to an administrative agency "if it appears that the matter involves technical or policy considerations which are beyond the court's ordinary competence and within the agency's particular field of expertise." *MCI Commc'ns Corp. v. AT&T Co.*, 496 F.2d 214, 220 (3d Cir. 1974); *see also Global Naps, Inc. v. Bell Atl.-N.J., Inc.*, 287 F. Supp. 2d 532, 548-549 (D.N.J. 2003) (Greenaway, J.). "When an activity is arguably subject to an administrative agency's expertise . . . federal courts must defer to the exclusive competence of that agency." *In re Human Tissue Prod. Liab. Litig.*, 488 F. Supp. 2d 430 (D.N.J. 2007) (Martini, J.); *see also Newton v. Pub. Serv. Elec. & Gas Co.*, A-5569-07T4, 2009 N.J. Super. Unpub. LEXIS 352, at *11 (N.J. App. Div. Jan. 23, 2009).

In determining whether primary jurisdiction is applicable, courts generally consider whether: (1) the matter at issue is within the conventional experience of judges; (2) the matter is peculiarly within the agency's discretion, or requires agency expertise; (3) an inconsistent ruling might pose the danger of disrupting the statutory scheme; and (4) prior application has been

made to the agency. *IPCO Safety Corp.*, 944 F. Supp at 356; *Global Naps, Inc.*, 287 F. Supp. 2d at 549; *Torres-Hernandez v. CVT Prepaid Solutions, Inc.*, No. 08 Civ. 1057, 2008 U.S. Dist. LEXIS 105413, at *9 (D.N.J. Dec. 17, 2008); *Clark v. Actavis Group HF*, 567 F. Supp. 2d 711 (D.N.J. 2008) (Greenaway, J.); *Oh v. AT&T Corp.*, 76 F. Supp. 2d 551, 557 (D.N.J. 1999) (Walls, J.); *Newton*, 2009 N.J. Super. Unpub. LEXIS 352, at *11; *Richardson v. Standard Guar. Ins. Co.*, 853 A.2d 955, 971 (N.J. App. Div. 2004).

When, as here, the resolution of a contested legal issue turns on factual issues within the special province of an administrative agency such as the USDA, courts routinely refer the disputed factual issue to the agency. In *Heller v. Coca-Cola Co.*, 230 A.D.2d 768, 646 N.Y.S.2d 524 (N.Y. App. Div. 1996), for example, the appellate court affirmed the dismissal on primary jurisdiction grounds of a deceptive business practice claim alleging that soft drinks that contained Aspartame "had become spoiled, stale, or tasteless, due to the limited shelf life of Aspartame," and seeking to compel disclosure of "the 'use by' or expiration dates on all diet soft drinks." *Id.* at 768. The court found deferral to the FDA appropriate given the agency's extensive review of Aspartame and its stability, and the agency's promulgation of labeling requirements for Aspartame which did not include "use by" or expiration dates. The court noted that deferral to the FDA "will ensure that there will be national uniformity in the labeling of Aspartame and will utilize the special expertise of the FDA in evaluating the relevant factors for approving food additives. This is especially true given the fact that FDA considered for over a decade the stability characteristics of Aspartame." *Id.* at 770.

New Jersey courts have reached similar results. Thus, in *Boss v. Rockland Electric Co.*, 468 A.2d 1055 (N.J. 1983), a dispute arose over a utility's plans to clear trees from private property crossed by the utility's easement pursuant to grant language which defined the parties'

rights in terms of what is "necessary for the proper operation and maintenance of said system." *Id.* at 1058. The Supreme Court of New Jersey determined that the public utility board was charged with determining what was necessary and safe for the maintenance of the system and that, "where the resolution of a contested legal issue properly brought before a court necessarily turns on factual issues within the special province of an administrative agency, the court should refer the factual issues to that agency." *Id.* at 1060. *See Richardson,* 371 853 A.2d at 971 (applying primary jurisdiction doctrine to refer a claim regarding marketing activity of insurers and the content of their policies and rates charged because claim fell within realm of administrative agency's expertise and also posed risk of disrupting regulatory scheme through inconsistent rulings).

The claim at issue here just as clearly falls squarely within the realm of an administrative agency's experience and expertise spanning over a hundred years, and bypassing that experience poses the same risks of confusion and the disruption of an intricate and important regulatory scheme. The FMIA regulates the nation's commercial supply of meat to ensure that the products are safe, wholesome, and correctly labeled and packaged and the USDA is charged with enforcing it. To that end, the FMIA provides for the Secretary of Agriculture to prescribe labeling requirements to avoid false or misleading labeling, as well as definitions and standards of identity or composition wherever the Secretary determines such action is necessary to protect the public. 21 U.S.C. §607(c). Over the last 100 years, both the USDA and FDA have sponsored original research, convened expert panels and studied extensively claims that products with nitrate and nitrites contribute to cancer or are carcinogenic before determining that nitrate/nitrates were safe when added to food. While the agencies have established limits on their use, neither agency has revoked the long-standing approvals of these substances or deemed

it necessary or appropriate to ban their use in meat products. Moreover, the USDA has not deemed it necessary or appropriate to include on USDA-approved packaging or labels for processed meats, the type of warning that Plaintiffs here ask the Court to impose.

This case also potentially presents a number of medical and epidemiological issues that courts have long-recognized as particularly within the experience and expertise of government administrative agencies and not the courts. *See Pub. Citizen v. Foreman*, 631 F.2d 969, 977 (D.C. Cir. 1980) ("The use of nitrites in curing bacon presents difficult medical and scientific questions. Some believe that use of nitrites causes cancer while others claim nitrites are needed to prevent botulism. Such questions go beyond our competence, and we must defer to the administrative agencies with their technical expertise on these matters."); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) ("[T]he average consumer cannot be expected to analyze and weigh each conflicting study. The FDA possesses the requisite know-how to conduct such analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug."); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) (The FDA "as distinguished from a court, possess superior expertise, usually of a complex scientific nature."). The need to draw upon agency, rather than judicial, expertise in this area remains.

In order to prevent dislocating an intricate regulatory structure governing a sensitive industry, to insure that the purpose of the FMIA is carried out, and to allow the informed expertise of the USDA to determine whether processed meats pose a health hazard sufficient to warrant warnings of the nature advocated by Plaintiffs, this Court should invoke the primary jurisdiction doctrine. The relief sought by Plaintiffs, if granted, would impose a separate duty on Defendants in the State of New Jersey for products that are shipped nationwide and advertised

across state lines in national media. An order from this Court requiring the warnings Plaintiffs request obviously would not prevent another state, or another court, or the USDA or FDA, from requiring different labels on processed meat products sold in other jurisdictions, creating a powerful potential for inconsistent results and piecemeal regulation of these products. *See In re Human Tissue Products Liability Litigation*, 488 F. Supp. 2d 430 (D.N.J. 2007); *Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042, 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. Nov. 22, 2000).

Applying the primary jurisdiction doctrine to this matter not only would promote uniformity and consistency in the regulation of the meat industry, but also would draw on the USDA's specialized knowledge regarding the manufacturing, labeling and packaging of meat products, and thereby allow the agency entrusted with the regulation of meat to exercise its administrative discretion, all fundamental purposes of the primary jurisdiction doctrine.[6] Consequently, to the extent Plaintiffs' claims are found not to be preempted by the FMIA, this Court should dismiss this action pursuant to the primary jurisdiction doctrine so that the USDA can consider the intricate factual issues underlying Plaintiffs' claim. *See Tassy v. Brunswick Hosp. Ctr., Inc*., 296 F.3d 65, 68 (2d Cir. 2002) (the concern of consistency and uniformity is more prevalent in cases involving issues of broad applicability).

III. PLAINTIFFS' EXCLUSIVE REMEDY IS UNDER THE NEW JERSEY PRODUCTS LIABILITY ACT AND THEY HAVE NOT ALLEGED THE PHYSICAL INJURY NECESSARY TO STATE A CLAIM UNDER THAT ACT.

Even if this Court determines that neither the preemption doctrine, nor the primary jurisdiction doctrine applies to the claim here, the Complaint still must be dismissed. Under New Jersey law, any claim for alleged harm related to consumer products must be brought under

[6] On October 9, 2008, The Cancer Project, which is also Plaintiffs' counsel of record in this case, filed a Petition To The United States Department Of Agriculture For Enforcement And Rulemaking requesting that the USDA undertake a rulemaking to investigate the health effects of ingestion of processed meats and to curtail the availability of such meats in schools. This petition apparently remains pending before the USDA.

the New Jersey Product Liability Act ("PLA") and not under the CFA as Plaintiffs have alleged here. Even if Plaintiffs had attempted to proceed with a PLA claim, dismissal would be necessary because they have not and cannot allege the physical injury resulting from Defendants' conduct necessary to state a claim under the PLA.

The Supreme Court of New Jersey has explicitly held that the PLA subsumes all claims of harm related to consumer products to the exclusion of such claims under the New Jersey Consumer Fraud Act ("CFA").[7] *Sinclair v. Merck & Co., Inc.*, 948 A.2d 587 (N.J. 2008). The court noted that

> [T]he Legislature expressly provided in the PLA that claims for "harm caused by a product are governed by the PLA irrespective of the theory underlying the claim. We explained in [*In re Lead Paint Litigation*, 924 A.2d 484 (N.J. 2007)], *supra*, that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products."

Id. at 595. The court went on to hold that, "despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product" and a separate claim under the CFA is not allowed. *Id.* at 596.

The facts in *Sinclair* were straightforward. Plaintiffs sued Merck seeking the formation of a medical monitoring class for persons allegedly at "enhanced risk of serious undiagnosed and unrecognized myocardial infarction. . . and other latent injuries" due to having taken the medication Vioxx for a prolonged period. *Id.* at 589. Plaintiffs alleged violations of the PLA and the CFA. The court initially dismissed the PLA claim because plaintiffs had failed to allege any physical injury. The court then dismissed the CFA claim because "[t]he heart of plaintiffs'

[7] The only two exceptions to this rule are actions for harm caused by breach of an express warranty, N.J. Stat. Ann. § 2A:58C-1b(3), and environmental tort actions, N.J. Stat. Ann. § 2A: 58C-2, neither of which are applicable here.

case is the potential for harm caused by Merck's drug. It is obviously a product liability claim" and may not be maintained absent physical injury.

This Court reached the same conclusion in *Delaney v. Stryker Orthopaedics*, No. 08 Civ. 03210, 2009 U.S. Dist. LEXIS 16865 (D.N.J. Mar. 5, 2009) (Cavanaugh, J.). In *Delaney*, plaintiff's suit arose from the failure of a hip replacement implant. *Id.* at *20. Count Eight of the Complaint alleged a violation of the CFA because Defendant marketed its products as safe and effective, allegedly failed to disclose to the public Defendant's knowledge of the health hazard posed by the use of the products and allegedly concealed the health hazards created by the use of their products in connection with the sale and advertisement of the products. Delaney Compl., C.A. No. 08-03210, (Dkt. No. 1, Ex. A) at Count VIII, ¶ 3. Plaintiff sought to recover under the CFA the money he paid for the hip replacement device. *Delaney*, 2009 U.S. Dist. LEXIS 16865, at *20. The Court granted defendant's motion to dismiss the CFA count, finding that "[t]he PLA provides the sole method of prosecuting a New Jersey consumer fraud claim when the claim is based on harm caused by a product." *Id.*

In this case as well, Plaintiffs' claim is a "products liability claim" that must be brought under the PLA, if at all. Plaintiffs allegedly purchased and presumably consumed an unidentified quantity of hot dogs and thus, according to their Complaint, have subjected themselves to an increased risk of cancer. They maintain that "[d]efendants had a duty to warn their customers about the risks associated with consumption of their products." Compl. ¶ 9.[8]

[8] Plaintiffs allege, Compl. at ¶ 48, that:

> Defendants have failed to provide clear, reasonable, and adequate information and warnings to their wholesale and retain consumers about the risks of consumption of Defendants' processed meat products and associated exposure to known and/or probably carcinogens. Without information for consumers to effectively evaluate the comparative safety and healthfulness of these products, Defendants fail to protect the public against unreasonable risks of injury from their products.

"This classic articulation of tort law duties, that is, to warn of or to make safe, is squarely within the theories included in the PLA." *In re Lead Paint Litig.*, 924 A.2d 484, 503 (N.J. 2007). Put slightly differently, because "the heart of plaintiffs' claim is the potential harm caused by" defendants' products, Plaintiffs must pursue their remedy under the PLA, not the CFA. *See Sinclair*, 948 A.2d 587, *supra*.

Because Plaintiffs have only pled a CFA claim, their Complaint must be dismissed. Even if they had pled a claim under the PLA, moreover, it too would not survive dismissal because, as in *Sinclair and Delany*, Plaintiffs have not alleged a physical injury, *see* Compl. ¶¶ 21-23, a necessary predicate to a cause of action under the PLA. *See, e.g., Sinclair,* 948 A.2d 587, *supra* (no cause of action for medical monitoring under the PLA). As in *Sinclair*, a risk of future or latent injury simply is not a cognizable claim under either the CFA or the PLA[9] and Plaintiffs' Complaint should be dismissed with prejudice.

IV. PLAINTIFFS FAIL TO STATE A CLAIM UNDER THE NEW JERSEY CONSUMER FRAUD ACT.

If this Court ultimately considers the sufficiency of Plaintiffs' allegations, the Complaint must be dismissed for failure to state a claim under the CFA. To survive a motion to dismiss in federal court, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 129 S. Ct. 1937, 1949 (2009), *quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955 (2007). For a claim to be plausible on its face, it must plead facts that would allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949, citing *Twombly*, 550 U.S. at 556. While all well-pleaded facts are accepted as true, *Marangos v. Swett,*

[9] It is of no moment that Plaintiffs have not alleged a cognizable claim of any harm, only alleged possible future harm. In such an instance, the simple fact that Plaintiffs are attempting to assert a claim involving harm (even if not cognizable) puts the claims squarely under the rubric of the PLA instead of the CFA, just as the court in Sinclair found.

No. 08-Civ. 4146, 2009 U.S. App. LEXIS 13998, at **6-7 (3d Cir. 2009), *quoting Iqbal*, 129 S. Ct. at 1949, merely reciting elements of a claim supported by conclusory statements will not suffice, and such statements are not to be assumed true. *Rait v. Sears, Roebuck and Co.*, No. 08 Civ. 2461, 2009 U.S. Dist. LEXIS 70217, at **5-6 (D.N.J. Aug. 11, 2009), citing *Iqbal*, 129 S. Ct. at 1949. A complaint must state facts that raise the right to relief above the speculative level; a complaint which only allows the court to infer the "mere possibility of misconduct" from the well-pleaded facts is plainly insufficient. *Iqbal*, 129 S. Ct. at 1950, citing Fed. Rule Civ. Proc 8(a)(2); *Umland v. PLANCO Financial Servs, Inc.*, 542 F.3d 59, 64 (3d Cir. 2008).

A. Plaintiffs Have Failed to Plead Their Claim Under the Consumer Fraud Act With Sufficient Specificity.

In order to bring a private cause of action under the CFA, a plaintiff must plausibly allege three essential elements: (1) unlawful conduct; (2) an ascertainable loss; and (3) a causal relationship between the defendant's unlawful conduct and the plaintiff's ascertainable loss. N.J. Stat. Ann. § 56:8-2; *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009); *Parker v. Howmedica Osteonics Corp.*, 2008 U.S. Dist. LEXIS 2570, *6 (D.N.J. Jan. 14, 2008) (citing *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174 (N.J. App. Div. 2003)). Importantly, because a claim under the CFA is basically a fraud claim, "the pleading requirements of Rule 9(b) also apply." *Maniscalco v. Brother Intern. Corp. (USA)*, 627 F. Supp. 2d 494, 500 (D.N.J. 2009); *Slim CD, Inc. v. Heartland Payment Sys.*, No. 06-2256, 2007 U.S. Dist. LEXIS 62536, at *27 n.1 (D.N.J. Aug. 22, 2007) (citing *F.D.I.C. v. Bathgate*, 27 F.3d 850, 856 (3d Cir.1994)). The purpose is to provide defendants with appropriate notice of the precise misconduct that is alleged. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997); *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 491 (D.N.J. 1998).

Plaintiffs here have failed to adequately plead any element required under the CFA. More specifically, Plaintiffs have failed to plead with particularity either the violation or unlawful practice of which they are complaining or an ascertainable loss. They have not, moreover, properly pled a causal nexus between Defendants' alleged conduct and Plaintiffs' alleged loss.

B. Plaintiffs Fail to Allege That They Suffered An Ascertainable Loss.

A private plaintiff must plead "ascertainable loss" in order to have standing to bring a claim for consumer fraud under the CFA. *Weinberg v. Sprint Corp.*, 801 A.2d 281, 283 (N.J. 2002); *see also Laufer v. United States Life Ins. Co.*, 896 A.2d 1101, 1110 (N.J. App. Div. 2006) (ascertainable loss requirement is "purely a 'standing' requirement"); *Barrows v. Chase Manhattan Mortgage Corp.*, 465 F. Supp. 2d 347, 360-61 (D.N.J. 2006) ("[t]he CFA contains its own standing requirement[,]" which, under N.J.S.A. 56:8-19, requires that a plaintiff "present a claim of ascertainable loss"). In this context, an "ascertainable loss" is a "definite, certain and measurable loss, rather than one that is merely theoretical." *Bosland*, 964 A.2d at 749. Thus, the mere showing of a violation of the CFA is insufficient to entitle a private citizen to damages. *Dabush v. Mercedes-Benz USA, LLC*, 874 A.2d 1110, 1116 (N.J. App. Div. 2005) ("Simply showing a violation of the CFA . . . is insufficient to entitle a private citizen to damages under the Act. The CFA does not provide for recovery of statutory damages where a plaintiff cannot show actual harm.") (quotation marks and alterations omitted).

Plaintiffs' only attempt to allege "ascertainable loss" is in Paragraph 15 of the Introduction Section of their Complaint, where Plaintiffs allege payment of the purchase price for hot dogs by the Named Plaintiffs: "[N]amed Plaintiffs suffered an ascertainable loss, amounting to $900.00, the combined purchase price of Defendants' products." It is well-settled under New Jersey law, however, that the purchase price of Defendants' products is not the

appropriate measure of damages and therefore not an "ascertainable loss" within the meaning of the CFA's damages provisions. *See, e.g.*, *Parker*, 2008 U.S. Dist. LEXIS 2570, at *12 (plaintiff's payment of purchase price does not meet the "ascertainable loss requirement" with specificity required by Fed. R. Civ. P. 9(b)); *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 794 (N.J. 2005) ("The mere fact that [a] ... defect arises does not establish, in and of itself, an actual and ascertainable loss to the ... purchaser."); *Furst v. Einstein Moomjy, Inc.*, 860 A.2d 435, 441 (N.J. 2004) ("[P]urchase price neither represents the true value of the carpet nor plaintiff's ascertainable loss"); *Romano v. Galaxy Toyota*, 945 A.2d 49, 58 (N.J. App. Div. 2007) ("[T]he measure of plaintiff's ascertainable loss for CFA purposes cannot be the purchase price she paid for the automobile, but the difference between the vehicle she received and the vehicle as represented at purchase"); *Blatchford v. Kelly*, A-5947-07T1, 2009 N.J. Super. Unpub. LEXIS 1621, at *15 (N.J. App. Div. June 1, 2009) ("plaintiff must prove an ascertainable loss beyond the purchase price"). Only an actual "out-of-pocket" loss or a demonstration of loss in value" will suffice to meet the CFA's ascertainable loss hurdle. *Thiedemann*, 872 A.2d at 792-93 (because plaintiffs' vehicle repairs were performed under warranty at no cost to plaintiffs, plaintiffs did not sustain an ascertainable loss as there had been no out-of pocket loss or loss in the value of the vehicle). The Named Plaintiffs clearly do not allege that the products they purchased were worth less than the amount they paid, that they paid for something they did not receive, or that they suffered any out-of-pocket loss other than the purchase price. Indeed, Plaintiffs have alleged no loss at all, only fear of a possible future loss.

This Court dismissed a case just last year which constitutes compelling authority for dismissal of Plaintiffs' claim here. In *Parker v. Howmedica Osteonics Corp.*, purchasers of a hip replacement system that allegedly clicked and squeaked after being implanted, but which caused

them no physical injury, brought a CFA claim alleging that they had suffered an ascertainable loss consisting of the purchase price of the system, out-of-pocket medical tests and treatment, and future medical care and/or services due, apparently, to the manufacturer's failure to disclose already known defects in the product. 2008 U.S. Dist. LEXIS 2570 at *11. The court found that under the CFA neither the mere fact that a defect arises nor the payment of the purchase price of a product constitutes an ascertainable loss. *Id.* The court noted that while medical care costs theoretically could constitute an ascertainable loss, Plaintiffs had suffered no injury and had alleged no facts indicating they had undergone any medical tests or treatments associated with the use of the hip replacement system. *Id*. at *12-13. Allegations of costs associated with possible future medical care were too speculative to constitute a quantifiable loss. *Id.* at *13. Consequently, the allegations failed to meet both the CFA and the Rule 9(b) requirements, and dismissal was required. *Id*. at *11.

The only other allegation of any "damage" made by the Named Plaintiffs in the instant case, although not specifically referred to as an "ascertainable loss," is the claim that they were "denied an opportunity to make an informed decision about the level of risk [they were] willing to take, to decide not to purchase Defendants' processed meat products based on the associated cancer risk, and to instead purchase a healthful product" and were "thus damaged by Defendants' violations of the Act." Compl. ¶¶ 21-23. The denial of an opportunity to make an informed decision, however, is hardly a loss that is "quantifiable or measurable," *see Bosland*, 964 A.2d at 749, and the Named Plaintiffs make no attempt to do so in their Complaint or otherwise.

The Named Plaintiffs' failure to plausibly plead any "particulars" regarding a cognizable ascertainable loss or to provide factually supported allegations that they have sustained any loss at all, is fatal to their claim. *See Parker*, 2008 U.S. Dist. LEXIS 2570, at **12-13 ("When a

plaintiff fails to give particulars regarding their ascertainable loss, and when they offer broad and conclusory allegations, the ascertainable loss requirement has not been met."); *see also Franulovic v. Coca-Cola Co.*, Nos. 07-539, 07-828, 2007 U.S. Dist. LEXIS 79732 at *23-24 (D.N.J. Oct. 25, 2007) (plaintiff's "conclusory statement that she and other consumers have suffered an 'ascertainable loss' is insufficient" because she "actually received a beverage for her money, and she has not alleged how the purchase of that beverage constituted a specific loss"); *Solo v. Bed Bath & Beyond, Inc.*, No. 06 Civ. 1908, 2007 U.S. Dist. LEXIS 31088, at *10 (D.N.J. Apr. 26, 2007) (ascertainable loss requirement not satisfied where plaintiff failed to specifically allege that the sheets he received were worth less than he was promised).

Another recent decision by this Court, *Koronthaly v. L'Oreal USA, Inc.*, No. 07 Civ. 5588, 2008 U.S. Dist. LEXIS 59024 (D.N.J. July 29, 2008), is directly on point. In *Koronthaly*, plaintiff's CFA claim arising out of defendants' sale of lipstick that contained dangerous levels of lead was dismissed. *Id.* at *2. The Court rejected plaintiff's argument that the fact she would not have bought the lipstick if she had been made aware of its lead content constituted an injury in-fact or ascertainable loss. *Id.* at **12-14. Plaintiff did not allege any facts supporting an argument that the lipstick products were of lesser value because of their lead content, and even if she had, the Court concluded that such "purely subjective allegation of harm" would be insufficient to state a claim under the CFA. *Id.* at *14.

Because the Named Plaintiffs have not and cannot allege an "ascertainable loss" within the meaning of the CFA, they lack standing and the Complaint must be dismissed. *See Kauffman v. The Dreyfus Fund, Inc.*, 434 F.2d 727, 734 (3d Cir. 1970) ("A plaintiff who is unable to secure standing for himself is certainly not in a position to fairly insure the adequate representation of those alleged to be similarly situated.") (quotation marks omitted); *PBA Local No. 38 v.*

Woodbridge Police Dept., 134 F.R.D. 96, 100 (D.N.J. 1991) ("If it is ascertained that no named plaintiff has standing to sue, the complaint must be dismissed, and the propriety of certifying the class is an issue which need not be reached.")

C. Plaintiffs Have Failed to Allege Any Unlawful Practice By Defendants.

In trying to articulate some unlawful practice by Defendants giving rise to a duty to warn, Plaintiffs have failed to allege with sufficient particularity (1) which "processed meat products," other than Defendants' brand-named hot dogs, require additional warnings on labels and/or point-of-sale advertising, (2) why and how each Defendant's product, or specific ingredient or additive contained within the product, relates to the studies cited in the Complaint, (3) what quantities of a specific ingredient or additive in a product trigger Defendants' obligation to warn, and (4) why the same warning label would be appropriate for all "processed meat products" manufactured by Defendants.

Defendants are not required to guess at the answers to these questions simply because Plaintiffs have chosen to file a legally inadequate complaint. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997); *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 491 (D.N.J. 1998). "Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to 'defendants'." *Id.* A plaintiff must plead fraud with particularity with respect to each defendant, thereby informing each defendant of the nature of its alleged participation in the fraud. *Id.* Under Rule 9(b), pleadings containing collectivized allegations against "Defendants" simply do not suffice. *Naporano Iron & Metal Co. v. Am. Crane Corp.*, 79 F. Supp. 2d 494, 511 (D.N.J. 1999); *see also Seville*, 742 F.2d at 791; *Strange v. Nationwide Mut. Ins. Co.*, 867 F. Supp. 1209, 1220 (E.D. Pa. 1994) (complaint alleging that defendants' agents made fraudulent representations did not satisfy particularity requirements of Rule 9(b));

Jackson Nat'l Life Ins. Co. v. Ligator, 949 F. Supp. 200, 208 (S.D.N.Y. 1996) (citing plaintiffs' failure to distinguish among the "Ligator Defendants" as an egregious example of "group pleading" prohibited under Rule 9(b)).

Throughout their Complaint, Plaintiffs allege vaguely and non-specifically that consumption of "Defendants'" processed meat products and ingredients, such as nitrites, which are used in the preparation and preservation of these products, are associated with increased risks of colorectal cancer and other forms of cancer. Compl. ¶¶ 4, 31-41. The Complaint refers to published studies and reports that purport to associate consumption of processed meat products with an increased risk of cancer, but none which specify the kinds of processed meat products included in the studies or whether any of the Defendants' products were among the food products consumed and studied. *Id.* ¶¶ 1, 3-7, 31-39. Further, while the Complaint alleges the frequency with which the Named Plaintiffs *purchased* Defendants' hot dogs, *id.* ¶¶ 21-23, it is silent regarding the frequency or quantity of hot dogs actually consumed, even though the only frequency and quantity of processed meat consumption associated with an increased cancer risk alleged in the Complaint was a "daily intake of 25 grams of processed meat." *Id.* ¶ 7. Plaintiffs, in other words, have not even connected their purchase of Defendants' hot dogs to the consumption levels of processed meat alleged to lead to increased health risks. Nonetheless, based on these undifferentiated, "group" allegations, Plaintiffs seek injunctive relief mandating a warning and declaratory relief with respect to all of Defendants' processed meat products, *id.* ¶ 17. This complete failure to plead with particularity any individual or cognizable claim requires dismissal of the Complaint.

D. Plaintiffs Cannot Allege A Causal Relationship Between Defendants' Alleged Unlawful Conduct And Plaintiffs' Alleged Loss.

In addition to showing an ascertainable loss, Plaintiffs also must show that the loss occurred "as a result of" the conduct that is alleged to violate the CFA. N.J. Stat. Ann. § 56:8-19; *Thiedemann*, 872 A.2d at 791 ("[T]he limiting nature of the [ascertainable loss] requirement allows a private cause of action only to those who can demonstrate a loss attributable to conduct made unlawful by the CFA."); *Miller v. Am. Family Publishers*, 663 A.2d 643, 648 (N.J. Ch. Div. 1995) ("[T]here must be a 'causal relationship' between the unlawful practice and the 'ascertainable loss' sustained by the plaintiff."); *see also Solo*, 2007 U.S. Dist. LEXIS 31088, at *11.

Plaintiffs have failed to plead Defendants' unlawful conduct or Plaintiffs' ascertainable loss sufficiently to state a CFA claim; even if they could do so, however, Plaintiffs have not plead a causal nexus between those two elements. The only remotely relevant allegation contained in the Complaint, that "[a]s a direct result of Defendants' unlawful and unconscionable consumer practices in violation of The Act, Named Plaintiffs suffered an ascertainable loss, amounting to $900.00, the combined purchase price of Defendants' products," Compl. ¶ 15, is a recitation of an element of the claim – a legal conclusion – and not a factually supported and legally sufficient allegation of causation. *See Parker*, 2008 U.S. Dist. LEXIS 2570, at *13; *Solo*, 2007 U.S. Dist. LEXIS 31088, at **12-13; *In re Toshiba America HD DVD Marketing and Sales Practices Litig.*, No. 09 Civ. 939, 2009 U.S. Dist. LEXIS 82833, at *40 (D.N.J. Sept. 11, 2009).

Plaintiffs' failure to plead a causal relationship between Defendants' alleged omissions and Plaintiffs' alleged loss requires the dismissal of their claim. *See, e.g., Franulovic*, 2007 U.S. Dist. LEXIS 79732 at *24, (dismissing CFA claim where named plaintiff failed to allege causal connection between defendant's allegedly false and misleading statements and named plaintiff's

alleged loss). Named Plaintiffs do not allege that Defendants' purported omissions impacted their decision to purchase or not purchase processed meats in any manner whatsoever. They allege only that they were "denied [the] opportunity to make an informed decision" when they purchased Defendants' processed meat products. Compl. ¶¶ 21-23. They also speculate on behalf of absent class members that "Upon information and belief, had Defendants truthfully informed consumers that consumption of their processed meat products likely increases a person's risk of developing colorectal and other cancers, many consumers would have avoided purchasing products that cause and increase risk of cancer by instead choosing healthier food products." *Id.* ¶ 10.[10] Such conclusory allegations cannot state a CFA claim.

As a matter of law, no causal relationship exists where plaintiff cannot or does not allege that he or she was induced to buy a product[11] by defendant's false and/or misleading statements or omissions. *See, e.g., Franulovic,* 2007 U.S. Dist. LEXIS 79732 at *25; *Solo,* 2007 U.S. Dist. LEXIS 31088, at *12. In *Solo,* for example, the plaintiff class alleged that defendant Bed Bath & Beyond made misrepresentations regarding the thread counts of its sheets. 2007 U.S. Dist. LEXIS 31088, at *12. In granting Bed Bath & Beyond's motion to dismiss, the district court

[10] Such highly conjectural supposition based on "information and belief" and unsupported by any facts to support that belief cannot satisfy the causal relationship element under Rule 9(b)'s specificity requirement. *See Shulton, Inc. v. Optel Corp.*, No. 85 Civ. 2925, 1986 U.S. Dist. LEXIS 19775, at *53 (D.N.J. Sept. 29, 1986) ("[T]he court cannot accept such serious allegations of fraud based solely on the "information and belief" of the plaintiff alone, without any elaboration as to the basis of that belief"); 2-9 Moore's Fed. Practice — Civil § 903[g] ("Pleadings alleging fraud usually may not be based on information and belief.").

[11] Though some cases in this Section relate to claims involving products, there is no inconsistency with the New Jersey Supreme Court's holding that the New Jersey PLA subsumes all product claims and that a claim involving harm from a product cannot be brought under the CFA. The cases cited in this Section either fall under the exceptions articulated in footnote 7 (such as breach of express warranty claims) or involve cases where there is no allegation of harm related to the product. When "[t]he heart of plaintiffs' case is the potential for harm caused by" the product at issue, "[i]t is obviously a product liability claim" and falls under the PLA and not the CFA. *See Sinclair*, 195 N.J. at 66.

explained that an adequate causal connection could only have been established if the named plaintiff had alleged that he was induced to purchase the products at issue as a result of the defendant's misrepresentations or that he would not have purchased the products if he had known the truth about the products. *Id.* at *12. Because plaintiff failed to make such allegations, the court granted defendant's motion to dismiss. *Id.* As explained by the court:

> Nowhere . . . does Plaintiff explain how this ascertainable loss is attributable to the unlawful conduct. Adequate explanations would include a statement by Plaintiff indicating that Plaintiff purchased the sheets in part because of the representation that the sheets were "1000 thread count," or, that Plaintiff would not have purchased the sheets had they been labeled with the actual thread count. . . . Plaintiff has not provided any such explanation of the connection between his alleged damages and the wrongful conduct of Defendants. As such, Plaintiff has failed to adequately plead the existence of a causal nexus between the alleged misrepresentations and his ascertainable loss, and his CFA claim and Amended Complaint must be dismissed.

Id.

Similarly, in *Franulovic*, the plaintiff class brought a claim against the manufacturers and distributors of a carbonated beverage for allegedly misrepresenting the weight loss benefits of the drink. 2007 U.S. Dist. LEXIS 79732, at *2. Because the named plaintiff did not allege that she relied on the alleged misrepresentations in purchasing the product, plaintiff's CFA claim was dismissed:

> Melfi does not allege that she purchased Enviga because of a certain misleading ad, or that she purchased the prescribed amount of Enviga and did not enjoy the advertised effects. . . . Instead, Melfi's claims generally state that Enviga's marketing was false and misleading, without alleging that this false advertising caused her a quantifiable loss. Consequently, as Melfi's Complaint stands now, because Melfi has not properly alleged an ascertainable loss or causation as required in order to maintain a CFA claim, Melfi's CFA claim must be dismissed.

Id. at *25-26.

Named Plaintiffs here do not maintain that Defendants' alleged omissions impacted their decision to purchase or not purchase processed meats in any manner. Instead, they simply allege that they were "denied [the] opportunity to make an informed decision" when they purchased Defendants' processed meat products. Compl. ¶¶ 21-23. Missing from the Complaint are any allegations that the Named Plaintiffs would not have purchased Defendants' products if they had known either of the presence of nitrites and *N*-nitroso compounds in processed meat products or of the reports that cancer risks may be associated with the consumption of those products. In the absence of such allegations, there simply is no causal relationship between Defendants' alleged omissions and any even theoretical loss suffered by Plaintiffs. *See, e.g., Franulovic,* 2007 U.S. Dist. LEXIS 79732 at *31-32. (dismissing CFA claim where named plaintiff failed to allege causal connection between defendant's allegedly false and misleading statements and any alleged loss).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court enter a finding that the Complaint is preempted under the Supremacy Clause of the Constitution of the United States and the FMIA by virtue of either the express preemption doctrine, the field preemption doctrine, or the implied conflict preemption doctrine. In the alternative, to the extent that any of Plaintiffs' claims are not preempted, they should be dismissed pursuant to the primary jurisdiction doctrine. Further, Plaintiffs' claim for alleged harm related to a consumer product should have been brought under the New Jersey Products Liability Act, but Plaintiffs cannot state a claim under that statute because they cannot allege any physical injury resulting from Defendants' conduct. Finally, if this Court ultimately considers the sufficiency of the allegations

in the Complaint, Plaintiffs' state law claim under the New Jersey Consumer Fraud Act should be dismissed in its entirety for failure to state a claim.

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Respectfully submitted,

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